

Application No.: 10/642,440

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MAY 16 2007**REMARKS**

Reexamination and reconsideration is respectfully requested in light of the foregoing amendments to the claims and the following remarks.

Applicant and its representatives appreciate the courtesy of the interview held with the Examiner and her Primary Examiner on May 15, 2007, wherein many of the issues with respect to this application were discussed and suggestions made by the Primary to advance prosecution.

Claims 1-40 are pending in this application. Claims 13-24 have been withdrawn from consideration due to a restriction requirement. New claims 37-40 have been added. Claims 1, 7 and have been amended as discussed *infra*. Claim 36 has been amended to add a missing bracket ("}") in the chemical formula between "-ylimino" and "-3-methyl-oxazolidin" in the seventh formula listed in the claim. Also, with respect to Example 44, bridging paragraphs [00157] and [00158] of the specification, the chemical name for the chemical structure has been amended to correct an obvious typographical error, namely, "[3,4,-d]-oxazol ..." should be -- [3,4]-doxazol --. Claim 31 has been amended to add a structure for Z found in claim 35.

Rejection Under Second Paragraph of 35 U.S.C. § 112

Claims 1-12 and 25-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The legal standard for indefiniteness is whether a claim reasonably apprises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), *cert. denied sub nom., Genetics Inst., Inc. v. Amgen, Inc.*, 112 S.Ct. 169 (1991). The definiteness of the language employed must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and the application disclosure as it

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would be interpreted by one possessing the ordinary level of skill in the pertinent art. *See In re Angstadt*, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976).

(a) The Examiner holds that the variable R^6 is indefinite because it can be combined with R^4 or R^8 to form a ring in which R^6 can be a substituent and that it is unclear as to what is the scope of R^6 . The same holding has been made for R^8 which can be combined with R^9 to form a ring. The Office Action does not state how and why a person having ordinary skill in the art would not have been apprised of the scope of the claim with respect to the claim as written. Such a person reading the specification would have been aware of the scope of the claims. Obviously, if R^6 forms a ring structure when combined with R^4 or R^8 , or R^8 forms a ring with R^9 , both R^6 or R^8 as recited in the claim are clearly single bond substituents that a person skilled in the art would have recognized could be substituted in the rings. The Office Action has not provided any cogent scientific reasoning as to explain why such a person would not this not to be the case.

(b) The Examiner finds claim 26 to be indefinite because it is not clear whether the Z is bonded to U via the N on the ring or through " $=N-$ ". The Examiner apparently has not recognized that the formula for Z has a divalent $=N$. Obviously, it should be trivalent, i.e., $=N-$, as recognized by the Examiner in her Office Action. This is an obvious error in the formula. Accordingly, the formula for Z in claims 1, 7 and 8 have been amended to include an additional bond to make the $=N$ trivalent to correct this obvious error.

(c) The Office Action asserts that claims 26-35 lack antecedent basis because claim 1 requires R^6 of Z to be -NH when W is O. The claim includes an obvious error since it was argued in the last response in the paragraph bridging pages 17 and 18 that the proviso in the

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claim was that NR⁶ of Z is not NH. Claim 1 has been amended to add the word "not" before "NH." It is believed that by amending the claims in this manner, the rejection of claims 26-35 for lack of antecedent basis is overcome.

(d) The Office Action maintains that claim 36 lacks antecedent basis "because it depends on claim 1 which recites species that are outside the scope of claim 1." This rejection is not understood. It is requested that the Examiner point out which of the listed compounds in the claim recites species not within the scope of claim 1.

For all of the foregoing reasons, it is respectfully requested that the rejection of claims 1-12 and 25-36 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Rejection Under the First Paragraph of 35 U.S.C. § 112

Claims 1-12 and 25-35 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking written description in that the term "solvates" does not have adequate description. The function of the written description requirement is to ensure that the inventors have possession, as of the filing date of the application, of the specific subject matter later claimed. *In re Edwards*, 568 F.2d 1349, 1351, 196 USPQ 465, 467 (CCPA 1978); *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). To comply with this requirement, it is not necessary that the invention be claimed using the same words as in the specification. All that is required is that the specification reasonably convey to a person of ordinary skill in the art that as of the filing date of the application, the inventors had possession of the subject matter later claimed. *In re Edwards*, 568 F.2d at 1351-1352, 196 USPQ at 467; *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96; *In re Lukach*, 442 F.2d 967, 969, 169 USPQ 795, 796 (CCPA 1971). The determination as to whether the specification provides support for the newly claimed subject matter is primarily

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factual and depends on the nature of the invention and the amount of knowledge imparted by the disclosure to those of ordinary skill in the art. *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96. The Examiner has the initial burden of presenting evidence or reasoning as to why one of ordinary skill in the art would not have recognized in the specification a description of the invention as later claimed.

The term "solvates" is part of the original disclosure. Therefore, this would have conveyed to a person having ordinary skill in the art that the inventors had possession of the claimed subject matter, "solvates" at the time the application was filed. Further, it is Applicant's position that a "solvates" is well known in the art and that a person skilled in the art would know how to make a solvate. However, in order to advance prosecution of the claims, the term "solvate" has been deleted from claim 1. Accordingly, it is respectfully requested that the rejection of the claim for lack of written description be reconsidered and withdrawn.

The claims have also been rejected as lacking enablement because of the expression "R² is a C₁₋₈ alkyl having a terminal carbon atom bound to one or the ring atoms of R¹" in claim 1. In response to this rejection, claim 1 has been amended to delete the objected to expression. It is believed that by this amendment, the rejection is overcome. It is respectfully requested that the rejection be reconsidered and withdrawn.

Obviousness-Type Double Patenting Rejection

Claims 1-12 and 25-35 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-7, 10, 20-91 and 101-106 of copending Application No. 10/914,974. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly

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claimed formula I overlaps with formula I of 10/914,974 when their variables represent the following:

- i. A is Z (of $-(U)_nZ$; $n = 0$);
- ii. X is N;
- iii. R^1 is a substituted or unsubstituted monocyclic or bicyclic aryl moiety;
- iv. R^2 is H or a substituted or unsubstituted C_{1-8} alkyl;
- v. Z is a 5-membered ring having N, V and W single/double bonded to N;
- vi. V is CR^7R^8 or CR^8R^8 .

Claim 1 has been amended so that the proviso for Z reads "NR⁶ of Z is not NH." It is believed that by this amendment, the rejection is overcome. The application relied upon by the Examiner does not claim the nitrogen in the ring as having any other substituent but hydrogen. Thus, it is Applicant's position that the claims of the present application would not be an obvious modification over the claims of the published application. Accordingly, it is respectfully requested that the Examiner reconsider and withdraw this rejection.

New Claims 37-40

New claims 37-40 have been added to define a subgeneric group of compounds. This was suggested by the Primary Examiner during the telephone interview on May 15, 2007. It is believed that the claims provide a genus within the scope of the working examples disclosed in the specification of the present application. The new claims do not add any new matter and are supported by Examples 31-48 in the specification and paragraph [0021] of the specification.

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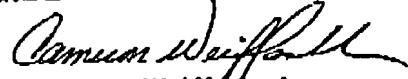
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MAY 16 2007**Conclusion**

For the foregoing reasons, it is submitted that the claims 1-2 and 25-40 satisfy the requirements of the first and second paragraphs of 35 U.S.C. § 112. Favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

A petition for a one-month extension of time under 37 C.F.R. § 1.136 is attached to this response along with a transmittal form. Please charge any shortage in fees due under 37 C.F.R. § 1.17 and due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,
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Michelle J. Bryant

Date: May 16, 2007